Saskatchewan Ministry of Health

Drug Plan and Extended Benefits Branch

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SASKATCHEWAN FORMULARY BULLETIN
UPDATE TO THE
58th EDITION OF THE
SASKATCHEWAN FORMULARY

The following listings are effective **April 1, 2009**, unless otherwise indicated.

NEW FULL FORMULARY LISTINGS:

- Blood glucose test strip (EZ Health Oracle-THI)
- Calcipotriol/betamethasone dipropionate, ointment, 50mcg/0.5mg/g (Dovobet-LEO)
- Lancet (EZ Health Oracle-THI)

NEW EXCEPTION DRUG STATUS LISTINGS EFFECTIVE JANUARY 1, 2009:

- Epoetin alfa, pre-filled syringe, 20,000 IU/0.5ml (Eprex-JAN)

For coverage according to the current criteria for epoetin alfa.

- Fosfomycin tromethamine, oral powder (sachet), 3g (Monurol-AXX)

For treatment of:
a) Urinary tract infections with organisms resistant to first line therapy.
b) Urinary tract infections in patients allergic to first line agents.
c) Urinary tract infections in pregnancy when first line agents are inappropriate.

Monurol was previously an EDS benefit but was removed from the Formulary in July 2007 when Purdue Pharma discontinued the product. Monurol is now available from Axxess Pharma, so has been reinstated as an EDS benefit drug.

- Skin preparation, wipe (IV Skin Preparation-MOC)

For coverage according to the current criteria for skin preparation products under the Saskatchewan Children's Insulin Pump Program.

NEW EXCEPTION DRUG STATUS LISTINGS EFFECTIVE MARCH 1, 2009:

- Ranibizumab, injection solution, 10mg/ml (Lucentis-NVR)

For treatment of neovascular (wet) age-related macular degeneration (AMD) if all of the following circumstances apply to the eye to be treated:
a) The best corrected visual acuity (BCVA) is between 6/12 and 6/96.
b) The lesion size is less than or equal to 12 disc areas in greatest linear dimension.
c) There is evidence of recent (<3 months) presumed disease progression (blood vessel growth, as indicated by fluoroscein angiography, optical coherence tomography (OCT) or recent visual acuity changes).
d) Injection will be by a qualified ophthalmologist with experience in intravitreal injections.

Coverage will not be provided for patients:
a) With permanent structural damage to the central fovea or no active disease (as defined in the Royal College of Ophthalmology guidelines).
b) Receiving concurrent verteporfin PDT treatment.

The interval between the doses should be no shorter than one month.

Treatment with ranibizumab should be continued only in people who maintain adequate response to therapy.
Ranibizumab should be permanently discontinued if any one of the following occurs:
a) Reduction in BCVA in the treated eye to less than 15 letters (absolute) on 2 consecutive visits in the treated eye, attributed to AMD in the absence of other pathology.
b) Reduction in BCVA of 30 letters or more compared to either baseline and/or best recorded level since baseline since this may indicate either poor treatment effect or adverse event or both.
c) There is evidence of deterioration of the lesion morphology despite optimum treatment over 3 consecutive visits.

NEW EXCEPTION DRUG STATUS LISTINGS EFFECTIVE APRIL 1, 2009:

- Ambrisentan, tablet, 5mg, 10mg (Volibris-GSK)

For treatment of pulmonary arterial hypertension, on the recommendation of a specialist.

- Desmopressin, orally disintegrating tablet, 240 mcg (DDAVP Melt-FEI)

For coverage according to the current criteria for desmopressin.

- Insulin glulisine (rDNA origin), solution for injection, 100U/ml (10ml vial); 100U/ml, pre-filled pen SoloSTAR (3ml) (Apidra-AVT)

For treatment of difficult to control diabetes in patients who have not responded to alternative agents listed in the Formulary.

- Lopinavir/ritonavir, tablet, 100mg/25mg (Kaletra-ABB)

For coverage according to the current criteria of other dosage forms of lopinavir/ritonavir.

- Maraviroc, tablet, 150mg, 300mg (Celsentri-PFI)

For treatment of HIV-1 disease (in combination with other antiretroviral agents) in patients:
a) Who have CCR5 tropic viruses **AND**
b) Who have documented resistance to at least one agent from each of the three major classes of antiretroviral agents (nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors and protease inhibitors).
Note: Testing for CCR5 tropic viruses is required for use of this agent. This drug, as with other antivirals in the treatment of HIV, should be used under the

direction of an infectious disease specialist.

- Rivaroxaban, tablet, 10mg (Xarelto-BAY)

a) For prophylaxis following total knee arthroplasty for up to 14 days following the procedure.
b) For prophylaxis in patients undergoing total hip replacement for up to 14 days following the procedure.

REVISED EXCEPTION DRUG STATUS CRITERIA:

- Efavirenz/emtricitabine/tenofovir disoproxil fumarate, tablet, 600mg/200mg/300mg (Atripla-BMY)

For treatment of HIV-1 infection where the virus is susceptible to each of tenofovir and emtricitabine and efavirenz and:
a) Atripla is used to replace existing therapy with its component drugs, or
b) The patient is treatment naïve, or
c) The patient has established viral suppression but requires antiretroviral therapy modification due to intolerance or adverse effects.
This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

- Emtricitabine/tenofovir disoproxil fumarate, tablet, 200mg/300mg (Truvada-GSI)

For treatment of HIV patients where:
a) The virus is susceptible to tenofovir and emtricitabine, **AND**
b) Efavirenz is not indicated due to adverse effects or antiretroviral resistance.
This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

- Iron sucrose injection, 20mg/ml (Venofer-GPM)

a) For treatment of iron deficiency when patients are intolerant to oral iron replacement products and intravenous iron dextran.
b) For treatment of patients who are intolerant to oral iron replacement products who require loading regimens of intravenous iron therapy.

NEW INTERCHANGEABLE FULL FORMULARY OR EDS LISTINGS:

- Azithromycin, oral suspension, 20mg/ml, 40mg/ml (Novo-Azithromycin-NOP)
- Dexamethasone phosphate, injection solution, 4mg/ml (Dexamethasone Omega-OMG)
- Morphine, sustained release tablet, 15mg, 30mg (Novo-Morphine SR-NOP)
- Niacin, tablet, 500mg, (Jamp-Niacin-JPC)

DRUGS RECENTLY REVIEWED AND NOT RECOMMENDED:

- Acamprosate calcium, delayed release tablet, 333mg (Campral-PRM)
- Ciclesonide, metered dose inhaler (nasal spray), 50ug/actuation (Omnaris-NYC)
- Dabigatran etexilate, capsule, 75mg, 110mg (Pradax-BOE)
- Methylnaltrexone bromide, injection solution, 20mg/ml (Relistor-WYA)
- Sitagliptin phosphate, tablet, 100mg (Januvia-MSD)
- Sodium oxybate, oral solution, 500mg/ml (Xyrem-VAE)

HEALTH CANADA RECOMMENDATION TO SUSPEND RAPTIVA (EFALIZUMAB) IN CANADA

In February 2009, EMD Serono Canada Inc., in consultation with Health Canada, suspended Raptiva from the Canadian marketplace due to safety concerns. Prescribers in Canada are advised not to issue any new prescriptions for Raptiva and should review the treatment of patients currently taking this drug to assess the most appropriate alternatives as soon as possible.

In consideration of this recommendation, the Drug Plan and Extended Benefits Branch advises that Raptiva will no longer be a benefit under the Drug Plan effective April 1, 2009.

Information on Health Canada's recommendation can be found at http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2009/raptiva_2_hpc-cps-eng.php .

REVISIONS TO THE SASKATCHEWAN CHILDREN'S INSULIN PUMP PROGRAM

Since July 1, 2007, the Saskatchewan Children's Insulin Pump Program (administered by the Drug Plan and Extended Benefits Branch of the Saskatchewan Ministry of Health) has provided assistance with the cost of insulin pumps and related supplies to children 17 years of age or younger who meet specific program criteria.

The medical criteria has been revised to provide more clarity for requisitioners and applicants. The Ministry of Health website has been updated to include this new criteria. To access this and other information about the Children's Insulin Pump Program, please visit the website at http://www.health.gov.sk.ca/insulin-pump-program.

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